| ΑD |      |
|----|------|
|    | <br> |

Award Number: DAMD17-00-1-0706

TITLE: The Impact of Relaxation and Hypnosis on Medical

Resources Utilization in Pediatric Asthma

PRINCIPAL INVESTIGATOR: Nancy H. Barber, Ph.D.

CONTRACTING ORGANIZATION: Brooke Army Medical Center

Fort Sam Houston, Texas 78234

REPORT DATE: October 2003

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;

Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

## REPORT DOCUMENTATION PAGE

Form Approved OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Ariington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

| 1. AGENCY USE ONLY  | 2. REPORT DATE        | 3. REPORT TYPE AND DATES COVERED    |   |  |
|---|-----------------------|-------------------------------------|---|--|
| (Leave blank)   | October 2003          | Annual (1 Oct 2002 - 30 Sep 2003)   |   |  |
| 4. TITLE AND SUBTITLE The Impact of Relaxation Resources Utilization in | -· ·                  | 5. FUNDING NUMBERS DAMD17-00-1-0706 |   |  |
| 6. AUTHOR(S)  |                       |                                     |   |  |
| Nancy H. Barber, Ph.D.  |                       |                                     | ·   |  |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)                      |                       |                                     | PERFORMING ORGANIZATION                         |  |
| Brooke Army Medical Cent  |                       | '                                   | REPORT NUMBER                                   |  |
| Fort Sam Houston, Texas  E-Mail: nancy.barber@cen.                      |                       |                                     |   |  |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)               |                       |                                     | SPONSORING / MONITORING<br>AGENCY REPORT NUMBER |  |
| U.S. Army Medical Resear<br>Fort Detrick, Maryland                      |                       | nd                                  |   |  |
| 11. SUPPLEMENTARY NOTES   |                       |                                     |   |  |
|   |                       |                                     |   |  |
| 12a. DISTRIBUTION / AVAILABILITY S                                      |                       |                                     | 12b. DISTRIBUTION CODE                          |  |
| Approved for Public Rele  | ase; Distribution Unl | imited                              |   |  |

## 13. ABSTRACT (Maximum 200 Words)

Asthma is one of the most common chronic pediatric illnesses. Estimates about its prevalence among children and adolescents under the age of 18 range up to 7%/Compared to their peers, children with asthma missed an additional 10.1 million days of school, had 12.9 million more contacts with physicians, and were hospitalized 200,000,000 more times in 1988. The estimated economic impact of asthma in the United States exceeds \$6.2 billion. Behavioral interventions have been shown to improve the management of pediatric asthma, as well as reduce the utilization of medical resources. The proposed study will determine if combining hypnosis and relaxation training interventions produces different medical resource utilization by pediatric asthma patients than the use of relaxation training alone. Twenty five pediatric asthma patients will be trained in relaxation techniques and self-hypnosis, twenty five will be trained in relaxation techniques alone and an additional twenty five patients will be receive no behavioral interventions. Medical resource utilization (clinic visits, emergency room visits, and hospitalization for asthma related events) will be examined in pre- and post-intervention for each group. Utilization will be compared between groups at 6 and 12 months following intervention. It is hypothesized that both intervention groups will demonstrate lower utilization postintervention, and that the hypnosis grp will demonstrate that least utilization of medical resources.

| 14. SUBJECT TERMS Pediatric asthma, hypr | 15. NUMBER OF PAGES 5                    |   |                            |
|--|--|---|----------------------------|
|  |  |   | 16. PRICE CODE             |
| 17. SECURITY CLASSIFICATION OF REPORT    | 18. SECURITY CLASSIFICATION OF THIS PAGE | 19. SECURITY CLASSIFICATION OF ABSTRACT | 20. LIMITATION OF ABSTRACT |
| Unclassified                             | Unclassified                             | Unclassified                            | Unlimited                  |

## **Table of Contents**

| Cover1                       |   |
|------------------------------|---|
| SF 2982                      |   |
| Table of Contents            | 3 |
| Introduction                 | 1 |
| Body                         | 4 |
| Key Research Accomplishments | 4 |
| Reportable Outcomes          | 4 |
| Conclusions4                 | 1 |
| References                   |   |
| Appendices                   |   |

INTRODUCTION: The purpose of this study is to examine the impact of behavioral medicine interventions on the medical utilization of pediatric asthma patients. It is anticipated that interventions of relaxation and self-hypnosis will decrease the costs associated with medical management of these patients. Patients who meet the inclusion criteria for the study, ages 8 through 12, whose parents give consent to participation, will be randomly assigned to one of the 3 intervention groups by the PI. As each subject is identified for the study, the PI will roll one dice in the presence of the research assistant. The numbers one or two will be assigned to the Hypnosis Group. Numbers three or four to the Relaxation Group, and numbers five and six to the Education Group. Each group will consist of 25 patients. None of the procedures in this research are Standard of Care; all procedures are adjunctive interventions to the standard of care and would not be performed if the participant were not in the study. The study will have a six and 12-month follow-up after the intervention.

BODY: Some progress has been made toward the statement of work. The Principle Investigator named in the original protocol, Dr. R. Garrison Barber, is no longer working for the institution and did not complete any data collecting for the study. He departed the institution in January 2002. Before his departure he had made contacts with the pediatricians about the study and did some preliminary work on setting up the forms to be used in the data collection. Since his departure, the protocol was closed at the local IRB level in the summer of 2002. In November 2002, Dr. Nancy Barber updated the original protocol and resubmitted it to the Brooke Army Medical Center IRB. The protocol was approved with minor revisions. In April 2003, the final approval was given by CIRO to proceed with the study. To date, contacts have been established with the Pediatricians and Pediatric Pulmonologists at Brooke Army Medical Center, the P.I. is attending the weekly Asthma Clinic to establish a liaison to recruit patients into the study. The research assistants have been trained in hypnosis, diaphragmatic breathing and progressive muscle relaxation and are ready to teach these techniques to patients as outlined in the protocol.

Recruitment of subjects for the study has been slower than expected. Recruitment began in June 2003. During the summer months of June, July and August 2003 the referral of patients to the study was limited. The recruitment process was undoubtedly effected by a disruption in personnel throughout the hospital due to the Iraq war. Deployments in the Department of Behavioral Medicine, Pediatrics Department and Pulmonology required resources and personnel to be temporarily redistributed to cover clinical duties left vacant by departing physicians and other active duty personnel. In addition, summer often brings a decrease in medical visits, fewer exacerbations of asthma related problems, and children being out of school and concurrently families being out of town.

KEY RESEARCH ACCOMPLISHMENTS: None

REPORTABLE OUTCOMES: None

CONCLUSIONS: Data collection is in progress. No conclusions to report at this time. A no-cost extension has been requested to continue with data collection.